US-PAT-NO: 5405614

DOCUMENT-IDENTIFIER: US 5405614 A

TITLE: Electronic transdermal drug delivery system

---------- KWIC ---------

Brief Summary Text - BSTX (30):
In accordance with yet a further feature of the invention, there is provided a pivotable **tab attached** to the cartridge, the pivotable **tab** having an extended position facing away from the cartridge for grasping the cartridge, and a closed position, closed into the cartridge.

Brief Summary Text - BSTX (34):
In accordance with again a further feature of the invention, the timing circuit is operative for activating the waveform generator in alternating on and off states in **programmed** sequence.

Brief Summary Text - BSTX (35):
In accordance with again an added feature of the invention, there are provided in the timing circuit EEPROM means for storing at least one timing **program** for timing the **programmed** sequence.

Brief Summary Text - BSTX (40):
In accordance with an additional feature of the invention, there are provided an access port connected to the EEPROM means, the access port operative for accessing external **programming** means for entering timing **programs** into the EEPROM.

Drawing Description Text - DRTX (10):
FIG. 5b is a view similar to FIG. 5a, but showing the cartridge with a closed **tab**;

Detailed Description Text - DETX (2):
Referring now to the figures of the drawing in detail and first, particularly, to FIG. 1 thereof, there is seen a wristband with an electronic base unit 1. As will be explained in the following, the electronic base unit 1 includes all of the necessary components of a wristwatch. A medicament cartridge 2 is placed in a center opening 1a provided in the base unit 1. The cartridge 2 is provided with a cartridge grasp **tab** 4. The cartridge 2 is held on the **tab** 4, **inserted** in the center opening 1a, and then rotated clockwise, as seen from the top.

Detailed Description Text - DETX (4):
The base unit is provided with a interface port 3. The port 3 allows direct direct **programming** access to the electronics of the base unit, by way of a computer interface jack 39. Electronic **programming, such as the programming** of an EEPROM through the interface jack 39 and the port 3 is well within the level of ordinary engineering skill in the electronics art. No detailed description of that feature is thus believed to be necessary.

Detailed Description Text - DETX (5):
Again referring to FIG. 1, the base unit is provided with user-operated control knobs 42. The control knobs 42 are used for accessing certain timer and display functions, which are generally known in the context of electronic watches. The knob 42 labeled BOLUS is of specific importance in this

invention. As explained in the description of the electronic circuitry, the BOLUS button is used to override the timed dispensing of drug actives, referred to a BASAL administration which is governed by the **programmed** timer functions.

Detailed Description Text - DETX (6):

Referring now to FIGS. 3a, 3b and 3c, which illustrate the cartridge 2 in top plan, front and right-side elevational views, respectively, a battery 8 is provided. In this embodiment, the battery 8 is a standard 3 volt dc battery. The **tab** 4 which is used for manually **inserting** and rotating the cartridge 2 in the base opening 1a, may be pivoted into a horizontal position as shown by a dashed line in FIG. 3c.

Detailed Description Text - DETX (7):

The horizontal position of the **tab** 4 is shown in FIG. 4, for instance. Also shown in that figure, wherein the cartridge 2 has been inserted in the opening 1a, but not yet rotated clockwise, is a compression spring 9 which biases a spring plate 10 downward towards a medicament 11 which is held in a collapsible medicament pouch or medicament enclosure 12.

Detailed Description Text - DETX (9):

With reference to FIGS. 5a-5d, the spring 9 and the spring plate 10 ensure positive pressure on the medicament enclosure 12, so that medication is administered even when the electronic wristband 1 is turned upside down. Contacts for the battery 8 are provided in a conventional manner, i.e. by means of a battery contact 13 and a battery flex plate 14. A ROM **chip** 15, the function of which will be explained in the following text and in the description of the circuitry, is placed in a space between

the battery
compartment and the compression spring 9.

Detailed Description Text - DETX (25):
A **programming** port 53 is provided for inserting timing instructions into the
EEPROM 51 from an external **programming** device.

Detailed Description Text - DETX (26):
The control module 50 includes a control circuit 54, for example a
microcomputer 54, or other **programmable** control device. The control circuit 54
is driven by a time reference 83 which supplies basic clock pulses driving the
control circuit 54 with a timing module 61, which drives a waveform generator
62 and a clock display 57. The control circuit 54 is connected with a patient
interface button set 58 which serves to manually enter timing instructions into
the EEPROM 51 via the control circuit 54. The control circuit 54 provides
drive signals for the dispenser driver 52 via electrical connections which are
realized by the contact set 7a in FIG. 1.

Detailed Description Text - DETX (27):
FIG. 13 shows parts of the control circuit 54, including the timing module
61, composed of a basal timing part 63, providing continuous timing for the
flow control device, and a time-limited bolus timing part 64, which overrides
the basal timing, and can be activated by the patient by operating the bolus
timing **key** 42 (FIG. 2). The bolus timing overrides the basal timing whenever a
drug dispensing **program** different from the basal timing is desired by the
patient. A waveform generator 62 provides the particular optimal signal
waveform used to drive the transducer 24.

Detailed Description Text - DETX (33):

In case the patient desires to alter the administration of medicament, e.g. to increase the amount being administered, or to reduce it, he activates the BOLUS knob or **key** 42 (FIG. 1), which causes the basal cycle to be interrupted and a bolus cycle of administrations to begin, as shown by the vertical dotted line 106, which indicates interruption of the basal cycle and beginning of a bolus cycle of "on" states 107, as shown in line "e". The duration of each bolus "on" state 107 is again controlled by instructions stored in the EEPROM 51. The bolus cycle is started by a bolus "start" pulse and is terminated by a bolus "stop" pulse 109. The bolus "on" state activates switch K4 in FIG. 14, and activation of the ultrasonic transducer 24. After the end of the bolus cycle at stop pulse 109, the basal cycle may be resumed, as it is **programmed** by the EEPROM to continue beyond the bolus cycle. The bolus "on" states are controlled by bolus hour pulses 111, as shown in line f.

Detailed Description Text - DETX (36):

FIG. 16b is a simplified block diagram of the timing module 61 (FIG. 12) in an embodiment that generates the on-state waveform for either the basal or the bolus timing in response to instructions **programmed** into the EEPROM 51. The timing circuit is composed of four cascaded ripple counters 101a, 101b, 101c and 101d driven by a 1/60 Hz, i.e. a one pulse per minute signal, from a time reference 83. Each counter has a respective output 102a-102d that represents a multibit output for each bit in the counter. Each counter is connected to one side of a respective comparator 103a-103d, while the other side of the counter is connected via multibit connections 104a-104d to a respective multibit word 106a-106d in the EEPROM 51. Each counter 101a-101d has a

counting input C and
a reset input R. Each counter reset input R is connected to an output E of a
respective comparator, so that when a counter reaches a count equal to the word
programmed to the EEPROM, the counters stops, and is reset and at the same time
activates a subsequent one of the other counters.

Detailed Description Text - DETX (37):
In that manner the timing circuit can be **programmed** to generate an output
control signal of any wave form determined by information **programmed** into the
EEPROM.

Detailed Description Text - DETX (38):
For the purpose of facilitating the following description of the operation
of the timing module, it is presumed that the timing cycle is based on a one
minute input (1/60 Hz) which is divided by 60 in the 101a counter, which
thereby generates a pulse each hour on lead 1 HR. The duration of the on-state
waveform is determined in counter 101b, which counts minute pulses until it
reaches the count **programmed** into EEPROM section 106b. If the on-state
condition is to be for example 20 minutes, a value equal to 20 is **programmed**
into EEPROM section 106b. After "start" at time t equal to 0 in FIG. 16c, when
counter 101b reaches a count equal to 20, a logic "1" appears on output E of
comparator 103b which sets a flip-flop 107b at its input pin S. The inverted
output Q inhibits the output of an AND-gate 108b driven by the minute input
1/60+12, and counter 101b stops counting, terminating the on-state output shown
at point 109 in FIG. 16c. Counter 101a continues to count to the count of 60
at which time a pulse is generated at output E of comparator 103a, which resets
minute counter 101a at input R, and also resets flip-flop

107b at input R.

Detailed Description Text - DETX (41):
It follows that the waveform can be controlled in all parameters with an accuracy of one minute, according to information **programmed** into the EEPROM 51.
It also follows that the timing need not be based on 60 minute hours or 24 hour cycles, since the hour and minute counters are also **programmed** into the EEPROM 51.

Detailed Description Text - DETX (42):
The bolus timing is performed by a similar counter which can be connected to EEPROM 51, or to another EEPROM if the bolus timing is desired to be different.
The bolus timing can be based on the same 1/60 Hz, i.e. one pulseper minute, driving the basal timing counter, but will during bolus timing be gated to generate its corresponding output wave form in response to operation of the BOLUS **key** 42 (FIG. 1), which is arranged to override the basal waveform shown in FIGS. 16c and 15, lines D and E. The bolus timing can advantageously be arranged to measure out only a single cycle of ON-states, by providing a counter control flip-flop (not shown) that is set only once by the BOLUS **key** 42, and is automatically reset as the last, for example, one of three hour ON-states, have elapsed.

Claims Text - CLTX (10):
9. The assembly according to claim 8, wherein said timing circuit is operative for activating said waveform generator in alternating on and off states in **programmed** sequence.

Claims Text - CLTX (11):

10. The assembly according to claim 9, including in said timing circuit
EEPROM means for storing at least one timing **program** for timing said **programmed**
sequence.

Claims Text - CLTX (16):
15. The assembly according to claim 10, including an access port connected
to said EEPROM means, said access port operative for accessing external
programming means for entering timing **programs** into said EEPROM.